Herb Safety

In general, it would appear that there are fewer adverse event reports (AERs) in the U.S. on a per capita basis for herbs than for conventional pharmaceutical drugs. On the other hand, it is also possible that the generally low incidents of AERs for herbs may be a result of poor reporting mechanisms and the possibility that many herb users simply may not report adverse events, because such events may be relatively minor (e.g., gastrointestinal upset, headache, etc.) and/or because many herb users may consider themselves outside the medical mainstream and may have a bias against making such a report. The truth of the situation in the U.S. is likely that both explanations are equally plausible; i.e, most commercially available herbs *are* generally gentler and safer than conventional drugs, *and* there needs to be better reporting mechanisms for herb-related adverse events.

The general safety of phytomedicines (advanced herbal preparations, often chemically standardized) has been well documented in Western Europe, where the regulatory systems in many countries treat herbs and phytomedicines in the same way as they treat conventional drugs. That is, phytomedicines are made from raw materials and extracts that meet national or the European pharmacopeia standards for identity and purity, they are required to be manufactured by proper good manufacturing practices (GMPs: the body of federal requirements governing how food or drug manufacturers must operate their production facilities in order to ensure safe, properly labeled consumer foods and drugs), they are evaluated and approved by national governments for indications as nonprescription drugs and for safety parameters (e.g., the German Commission E), and any adverse effects are routinely reported within the same pharmacovigilance system designed for conventional drugs. In the European Union, the AERs for herbs and phytomedicinal preparations are lower than the AERs for conventional drugs, even when adjusted for total doses sold.

There are several voluntary reporting systems for herb and dietary supplement-related AERs in the U.S. One is the American Association of Poison Control Centers in Washington, D.C., the results from which are available on fee-for-service basis, usually for companies who check on reports on their specific products. Another is the Food and Drug Administration's (FDA) MedWatch system for drugs, used primarily by health professionals (sometimes considered controversial insofar as the reports are not always fully documented with adequate information). A new, improved system at FDA for reporting adverse events related to foods and dietary supplements is managed by the agency's Center for Food Safety and Applied Nutrition (CFSAN) and is called CAERS (CFSAN Adverse Event Reporting System). CAERS is replacing the older and much less reliable Special Nutritionals/Adverse Event Monitoring System (SN/AEMS) which was created in 1998. There were many problems associated with poor documentation of AERs associated with AEMS, as was eventually acknowledged on the AEMS website before it was removed in August, 2002: "There is no certainty that a reported adverse event can be attributed to a particular product or ingredient. The available information may not be complete enough to make this determination."[1] The new CAERS system was expected to be pilot tested in 2003 and operational by 2004,[2] but is not yet online.

The FDA's 10-year work plan addresses the areas of safety, labeling, boundaries (related to appropriate definitions, etc.), enforcement activities, enhancement of the FDA's science/research capabilities, and outreach to consumers and manufacturers.[3] Included in the "Safety" section of the FDA's 10-year work plan, is the agency's commitment not only to publish regulations on GMPs, but also improve the AER system, as well as develop a database to enhance mechanisms for identifying potential health hazards related to foods and dietary supplements.[3] This is being implemented, as noted above.

The increasing use of herbs by consumers invariably suggests potential for interactions with conventional medications.[4,5,6] Eisenberg *et al.*[7] estimated that 15 million adults in 1997 used prescription drugs simultaneously with herbal remedies and/or high dose vitamin supplements, concluding that these persons were potentially at risk for adverse herb-drug or drug-supplement interactions. In a survey conducted by Princeton Survey Research Associates for *Prevention* magazine, researchers noted that 36% of herb users employ herbal remedies in place of prescription drugs; 31% *with* prescription drugs; 48% instead of over-the-counter (OTC) drugs; and 30% *with* OTC drugs.[8] In the Slone Survey[9] of 2590 participants from about the same period of time, 81% stated that they used at least one medication (Rx or OTC), 50% took at least one prescription drug, and 7% took five or more drugs simultaneously. Fourteen percent said they used herbs and supplements during the previous week while 16% of the prescription drug users acknowledged also taking an herbal supplement. These authors conclude that one in seven adults consume at least one herbal supplement annually and that one in six patients taking a prescription drug is concurrently taking one or more herbal supplements, raising the potential for interactions.

A recent systematic review of herb-drug interactions[6] concluded that of the 108 interactions evaluated, 74 cases (68.5%) were considered unable to be evaluated due to the lack of adequate information, 14 (13%) were considered "well-documented" and thus likely, and 20 (18.5%) were considered "possible" interactions. The authors emphasize the need for better documentation of all relevant data in case studies of potential interactions. The most authoritative, evidence-based database of herb-drug interactions has been compiled by Brinker.[10]

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